Response to CAP Vendor Questions

On August 3, 2005 CMS temporarily suspended bidding on CAP to provide additional time to more fully review comments to the CAP IFC and to implement further enhancements to the bidding process. In addition to the useful comments, we have also received a number of questions about the implementation of the program. We answered many of these questions in a posting on the CAP website on July 25, 2005. To provide further clarifications, below are the answers to several questions we have received about CAP. Additional questions we received about CAP would be best answered in the rulemaking context and we encourage the interested parties to submit comments to the IFC. These topics include the addition of new drugs to CAP, the process for adding additional NDCs, the mechanism for updating prices in years two and three of the contract, and financial standards for bidders.

Q. Does the ordering physician have ownership of the CAP drug once it has been delivered to the physician's office?

A. The CAP vendor maintains ownership of the drug until it is administered to the Medicare beneficiary. The drug may not be administered to anyone other than the beneficiary without, at a minimum, the permission of the vendor. As previously stated in the IFC, physicians are required to keep track of each CAP drug obtained for each beneficiary. However, this is not a requirement for physicians to physically maintain separate inventories. The physician merely has to track the drugs separately, either on paper or electronically.

Q. Will CMS allow the CAP vendor to file a claim for an unused portion of drug?

A. We expect that approved CAP vendors will furnish drugs and interact with physicians in a manner that will minimize unused drug. Specifically, we expect that physicians and approved CAP vendors will both make a good faith effort to order, label, ship, and store drugs in a manner that will allow the legal reuse of an unopened and intact container of a drug. Generally speaking, under the Average Sales Price system, a physician is able to bill the program for unused drugs if the physician acted in good faith with respect to the ordering and use of the drugs. We expect that vendors will be able to bill the program for unused drugs under the CAP program in a similar fashion if physicians and vendors act in good faith with respect to the ordering and use of the drugs. We expect further comments on the IFC with respect to how the CAP program can best encourage the efficient use of drugs while recognizing that some drugs will inevitably be unused in medical practice.

Q. How will the Coordination of Benefits be administered between the local Medicare carrier, the CAP vendor's designated carrier and the various Medigap insurers?

A. CAP will be the most successful when the physician, the beneficiary, the CAP vendor and the Medicare contractors work closely together on billing and other administrative concerns. We intend to support this process through Medicare's existing Coordination of Benefits processes. In the Interim Final Rule (page 39052 of the Federal Register) we describe how this process provides for the automatic crossover of many Medicare beneficiaries' claims to their supplemental insurance provider after Medicare has paid its portion of the claim. For beneficiaries with supplemental insurance, their coinsurance obligation is usually met through this automatic coordination of benefit process, so that the beneficiary is not required to pay the coinsurance at the time of service. In addition, the CAP vendor would not have the burden of billing the supplemental insurance since this would happen automatically.

As we discuss in the rule, we are currently consolidating the claims crossover process, on a national basis, to introduce standardization and efficiencies for the automatic crossover of claims to all participating supplemental insurers, including Medigap plans, employer retiree supplemental plans, TRICARE, and State Medicaid Agencies, for their use in calculating their financial liability after Medicare. Under this consolidated crossover process, supplemental insurers will execute a national Coordination of Benefits Agreement with a single CMS contractor, the national Coordination of Benefits Contractor (COBC), for purposes of receiving Medicare crossover claims. We expect that most supplemental insurers will participate in the national consolidated crossover process because of the consistencies and efficiencies that result from a standard national process. Participation by supplemental insurers will, in turn, result in standardization and efficiencies for suppliers, including CAP vendors, who seek reimbursement from these insurers. We are seeking further comments on how we can best support automatic coordination of benefits.

For individual circumstances when the crossover process is not applicable or there may be an issue with the coverage of the drug, we are exploring and seek comment on the appropriate role of the physician in facilitating the payment process. This might include voluntary activities requested by the vendor and the sharing of appropriate information with the vendor if agreed to by the beneficiary. All the voluntary activities requested by the vendor and undertaken by the physician would need to be consistent with existing laws and regulations including, among other things, the HIPAA privacy rule, the physician self-referral prohibition, the Federal anti-kickback statute, and any other state or federal law or regulation governing billing or claims submission. The activities requested by the vendor might include the collection of beneficiary coinsurance, the issuance of Advanced Beneficiary Notices in circumstances when the physician suspects that there may be an issue with the coverage of the drug, and notification to the vendor that the drug has been administered.